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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,374	01/12/2001	Robin James Spivey	R&G C- 317	1252

7590 03/10/2004
FLYNN, THIEL, BOUTELL & TANIS, P.C.
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EXAMINER

PADMANABHAN, KARTIC

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/760,374

Applicant(s)

SPIVEY ET AL.

Examiner

Kartic Padmanabhan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/5/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 January 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 32-41 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The immunoassay test membrane is critical or essential to the practice of the invention, but not included in the claim(s), thereby rendering the claims not enabled. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Applicant has recited that the screening device is for use with an immunoassay test membrane having various zones, but has not positively recited the test membrane as an essential part of the device. Although the test membrane is removable from the bracket of the device, it is nevertheless a critical component of the device and must be recited as such. Without this membrane, applicant cannot successfully carry out the function of the claimed device, which is to screen for a compound. Specifically, without the immunoassay membrane, there will be no light reflected from anything to compare to reference values, and there would be no way to determine the presence of anything. Therefore, applicant must positively recited the immunoassay test membrane with the test zone, control zone, and background zone, as well as the way in which each zone reacts to specimen application, in the body of the claim.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 32-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claims 32 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted element is the immunoassay test membrane because it is unclear if the membrane is a part of the device or not, and it appears to be critical component of the invention, without which the device cannot successfully function (see 35 USC 112, 1st paragraph rejection above).
6. Claim 32 recites the limitations "the presence" in line 3 of the claim, "the concentration" in line 5, and "the application" in line 7. There is insufficient antecedent basis for these limitations in the claim. In addition, in line 17 of the claim (last line of the clause relating to the detector assembly), applicant should insert "the" before "test membrane" because without that term, it is unclear to which membrane applicant is referring.
7. Claims 32 is also rejected as vague and indefinite for the recitation of first and second reference values to determine if the test is successful and to compare the concentration of light from the test zone because applicant has not recited the manner in which the reference values are determined. These values cannot be obtained arbitrarily, and as such, the ways in which the values are obtained are necessary to the claims. Further, the claim is vague and indefinite because applicant has not recited how a comparison of light from the control zone to the reference value is used to determine if the test is successful. In addition, if this comparison

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results in an unsuccessful test, what happens? Does the device continue with the other recited steps?

8. Claim 32 is further rejected as vague and indefinite because applicant has referred to a background zone in the claim, but has never recited any use for it whatsoever.

9. Claim 38 is rejected as vague and indefinite because it depends on claim 31, which has been cancelled.

10. Claim 40 is rejected as vague and indefinite because applicant has recited specific positions of the background zones and the manner in which light is reflected across various zones, but applicant has never positively recited the location of the various zones. Before referring to how light travels across the zones, applicant must positively recite the location of the various zones. In addition, the parent claim only refers to one of each type of zone (test, background, and control), so how can there now be multiple such zones? Applicant must significantly clarify the wording of this claim, as the exact limitations of this claim have not been adequately identified.

11. Claim 41 is rejected as vague and indefinite for the recitation of determining the position of the various zones based on the output signals because applicant has not recited the way in which this is done. In addition, in what way is this step correlated at all to a screening device? Do the location of the various zones have any effect on the operation of the device?

Response to Arguments

12. Applicant's arguments with respect to claims 32-41 have been considered but are moot in view of the new ground(s) of rejection.

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Conclusion

Claims 32-41 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 571-272-0825.

The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kartic Padmanabhan
Patent Examiner
Art Unit 1641



LONG V. LE
SUPERVISORY PATENT EXAMINER
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03/08/04